

(d) Reinstatement of exemption with respect to particular drug products**(1) Reinstatement**

On application by a manufacturer of a particular drug product that has been removed from exemption under subsection (a), the Attorney General shall by regulation reinstate the exemption with respect to that particular drug product if the Attorney General determines that the particular drug product is manufactured and distributed in a manner that prevents diversion.

(2) Factors to be considered

In deciding whether to reinstate the exemption with respect to a particular drug product under paragraph (1), the Attorney General shall consider—

(A) the package sizes and manner of packaging of the drug product;

(B) the manner of distribution and advertising of the drug product;

(C) evidence of diversion of the drug product;

(D) any actions taken by the manufacturer to prevent diversion of the drug product; and

(E) such other factors as are relevant to and consistent with the public health and safety, including the factors described in subsection (b) as applied to the drug product.

(3) Status pending application for reinstatement

A transaction involving a particular drug product that is the subject of a bona fide pending application for reinstatement of exemption filed with the Attorney General not later than 60 days after a regulation removing the exemption is issued pursuant to subsection (a) shall not be considered to be a regulated transaction if the transaction occurs during the pendency of the application and, if the Attorney General denies the application, during the period of 60 days following the date on which the Attorney General denies the application, unless—

(A) the Attorney General has evidence that, applying the factors described in subsection (b) to the drug product, the drug product is being diverted; and

(B) the Attorney General so notifies the applicant.

(4) Amendment and modification

A regulation reinstating an exemption under paragraph (1) may be modified or revoked with respect to a particular drug product upon a finding that—

(A) applying the factors described in subsection (b) to the drug product, the drug product is being diverted; or

(B) there is a significant change in the data that led to the issuance of the regulation.

(Pub. L. 91-513, title II, §204, as added Pub. L. 103-200, §2(b)(1), Dec. 17, 1993, 107 Stat. 2334; amended Pub. L. 104-237, title IV, §401(c), Oct. 3, 1996, 110 Stat. 3108; Pub. L. 109-177, title VII, §712(a)(2), Mar. 9, 2006, 120 Stat. 263.)

AMENDMENTS

2006—Subsec. (e). Pub. L. 109-177 struck out subsec. (e). Text read as follows: “Pursuant to subsection (d)(1) of this section, the Attorney General shall by regulation reinstate the exemption with respect to a particular ephedrine, pseudoephedrine, or phenylpropanolamine drug product if the Attorney General determines that the drug product is manufactured and distributed in a manner that prevents diversion. In making this determination the Attorney General shall consider the factors listed in subsection (d)(2) of this section. Any regulation issued pursuant to this subsection may be amended or revoked based on the factors listed in subsection (d)(4) of this section.”

1996—Subsec. (e). Pub. L. 104-237 added subsec. (e).

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104-237 not applicable to sale of any pseudoephedrine or phenylpropanolamine product prior to 12 months after Oct. 3, 1996, except that, on application of manufacturer of particular drug product, Attorney General may exercise sole and judicially unreviewable discretion to extend such effective date up to additional 6 months, see section 401(g) of Pub. L. 104-237, set out as a note under section 802 of this title.

EFFECTIVE DATE

Section effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103-200, set out as an Effective Date of 1993 Amendment note under section 802 of this title.

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

§ 821. Rules and regulations

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals.

(Pub. L. 91-513, title II, §301, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 103-200, §3(a), Dec. 17, 1993, 107 Stat. 2336; Pub. L. 108-447, div. B, title VI, §633(b), Dec. 8, 2004, 118 Stat. 2922.)

AMENDMENTS

2004—Pub. L. 108-447 substituted “listed chemicals” for “the registration and control of regulated persons and of regulated transactions”.

1993—Pub. L. 103-200 inserted before period at end “and to the registration and control of regulated persons and of regulated transactions”.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103-200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103-200, set out as a note under section 802 of this title.

EFFECTIVE DATE

Section effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91-513, set out as a note under section 801 of this title.

§ 822. Persons required to register**(a) Period of registration**

(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance